LABORATORIES QUALITY MANAGEMENT PLAN

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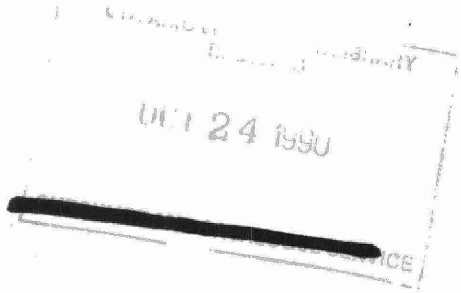

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MINISTRY OF ENVIRONMENT LABORATORY SERVICES

QUALITY MANAGEMENT PLAN

APPROVED BY:

G. C. Ronan, Director

DATE: Feb 28, 1990

CONCURRED WITH

S. Villard, Assistant Director

G. Kanert, Manager
Inorganic Trace Contaminants

J. Crowther, Manager
Water Quality

S. Villard, Manager
Drinking Water Organics

G. Crawford, Manager
Trace Organics

W. Cook, Laboratory Chief
London Regional Laboratory

S. Wisz, Manager
Administrative Services

S. MacBeth, Laboratory Chief
Kingston Regional Laboratory

J. Stasiuk, Manager
Utilities and Special Projects
Thunder Bay Regional Laboratory

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1. QUALITY MANAGEMENT PLAN

1.0 SCOPE

This Quality Management Plan (QMP) for the Ontario Ministry of the Environment, Laboratory Services Branch (LSB), and Regional Laboratories establishes formal responsibility on the part of the Section Managers, the Regional Laboratory Chiefs, the Quality Assurance Office, and staff, to develop and implement a comprehensive, verifiable Quality Assurance Program for the Central and Regional Laboratories. In Particular, it requires them to implement Quality Management Systems (QMS) which will ensure that staff are advised of their specific duties to maintain and document analytical data quality.

1.1 SIGNIFICANCE

Top-down assignment of responsibilities, and tasks is critical in establishing a management system. Strong management support is considered to be the essential ingredient which guarantees the success of a QMP.

This QMP, and the corresponding Section Quality Management Systems, establish a documented mechanism for communication and action. Managers, scientists and technicians have clearly defined roles designed to ensure the validity and integrity of the data being generated.

1.2 BACKGROUND

LABORATORY CLIENTS

As partners in program development, management and data interpretation, laboratory staff and clients must clearly identify three elements affecting quality:

i) a succinct statement of project objectives;

ii) specification of the program sampling and analysis elements required to meet the program Data Quality Objectives (DQOs);

iii) identification of the primary sources of data uncertainty, and evaluation of their relative importance in data interpretation.

These elements have an integrated impact on the quality of analytical data produced. They affect project design and the selection of appropriate field and laboratory operations.

Data quality, and therefore data interpretation, is affected by:

a) the variability of the environment being sampled and examined;

b) the uncertainty or bias introduced by the sampling process;

c) the uncertainty or bias introduced during field operations;

d) the bias introduced by sample transportation and storage prior to analysis;

e) the uncertainty or bias introduced by sub-sampling for analytical purposes;

f) the uncertainty or bias introduced by analytical sample pre-treatment or preparation;

g) the uncertainty or bias of measurement.

It is apparent that the interaction of these factors will affect the interpretation of data and the quality of individual results. Given a sufficiently large data set, it may be possible to determine and specify the relative significance of all these factors. The bias due to the analytical process must be minimized if the impact of the other factors is to be measured and, ultimately, controlled.

Therefore, the quality of laboratory operations is a priority concern.

It is essential that systems be established which define the level of quality to be achieved; the processes to be followed and the procedures required to document and report that quality.

1.3 ANALYTICAL QUALITY POLICY STATEMENTS

The Quality Management Plan (QMP) operates within the following policy statements:

1.3.1 All analytical services provided by LSB and Regional laboratories in support of programs of the Ontario Ministry of the Environment (OME), shall produce data of known quality which are appropriate to the particular program requirements and the nature of the analytical technology available for the types of samples involved.

1.3.2 The quality of all analytical data will be supported by appropriate documentation acceptable to the scientific community at large, and gathered in accordance with established ministry protocols.

1.3.3 The quality of the data will be achieved within the framework of an ongoing Quality Management System whereby staff responsibilities and operational procedures are defined, documented, and subjected to audit on a regular basis.

1.3.4 Laboratory Managers, Regional Laboratory Chiefs and Quality Assurance Office staff are responsible for the implementation of this Plan.

1.4 QUALITY MANAGEMENT GOALS

The goals of this Plan are as follows:

1.4.1 To ensure that the quality of analytical data is documented, and that it meets program quality requirements as defined by the DQOs developed by client and laboratory staff.

1.4.2 To ensure that the process for determining program DQOs is consistent within LSB and the Regional laboratories and that it is available for scrutiny.

1.4.3 To ensure that all activities expected within the framework of an effective Quality Assurance Program are identified and addressed.

1.5 QUALITY MANAGEMENT OBJECTIVES

To achieve the above goals, the Plan has the following objectives:

1.5.1 To ensure all necessary protocols and procedures, are documented, known to staff, and available for scrutiny.

1.5.2 To ensure all analytical systems are operated in accordance with established QA/QC protocols, that these are sufficient to maintain quality, and that timely corrective action is taken to resolve problems.

1.5.3 To ensure that regular reports on the quality of laboratory operations are prepared for management action as required.

1.5.4 To implement a process of independent audits of laboratory methods, records, and system performance, in order to verify that quality is being maintained.

1.5.5 To develop mechanisms for reporting QA/QC and related project-specific data quality information to laboratory clients and to assist them in data interpretation.

1.6 IMPLEMENTATION STRATEGY

The QMP will be implemented by laboratory management within the LSB and Regional laboratories through the establishment of Section Technical Committees (STCs).

The activities of the STCs will be developed by the Section QA Coordinators and the Quality Assurance Officer based on direction from the Managers QM Committee to maintain a consistent approach in the protocols and procedures being applied by all staff throughout the laboratories.

Note: Here, and in the remainder of this document, the word Section is intended to refer to organizational activities either at LSB or in the Regional Laboratories.

The progress of the Plan will be monitored quarterly by the Central/Regional Laboratories Quality Assurance Committee.

(A schematic of this implementation strategy is provided as Figure 1. Figure 2 provides details of the highlighted area on Figure 1).

1.7 BRANCH QUALITY MANAGEMENT DOCUMENTATION

The Quality Assurance Officer, in cooperation with the Section QA Coordinator, is required to prepare and maintain the following documents for review, approval and adoption by Laboratory Managers.

1.7.1 QA Policies and Guidelines

This document will delineate the generally accepted Good Laboratory Practices (GLPs), and other statements of normal operating conditions within LSB and Regional laboratories, which may impact on data quality, data reporting, or data interpretation. It provides the basis for Section Quality Assurance Programs, and QA Office and Section QA Workplans.

QUALITY MANAGEMENT PLAN
IMPLEMENTATION STRATEGY

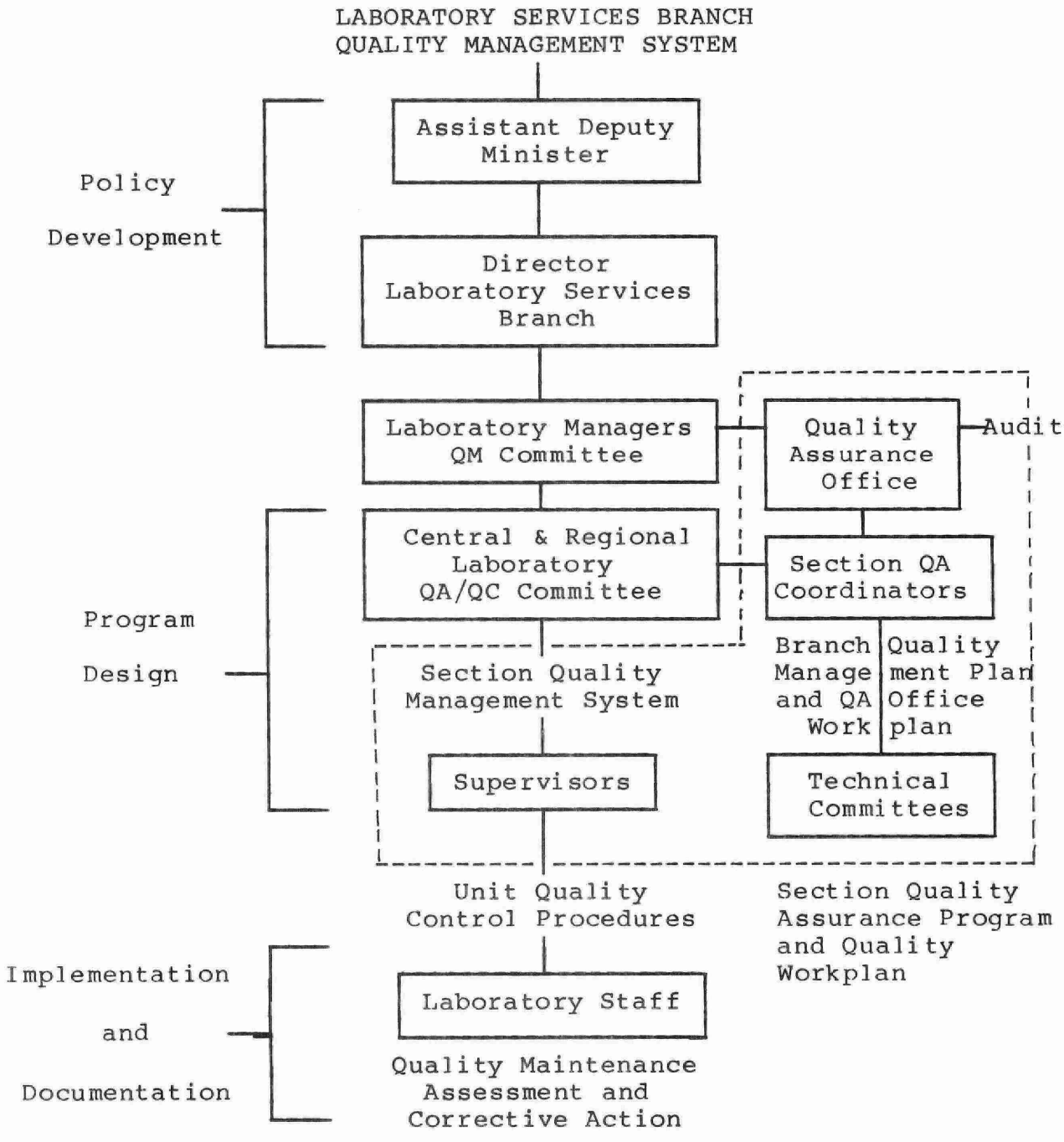


Figure 1

BRANCH
QUALITY ASSURANCE
PROGRAM
IMPLEMENTATION

IDENTIFICATION OF TASKS

PRIORITIES:

Method documentation
Performance assessment
Document QA activities by test
Document QC protocols
Computerization of QC data
On-line control assessment
Program audits
System audits
Performance audits
Problem solving - analytical
- operational
- sample validity
- test selection

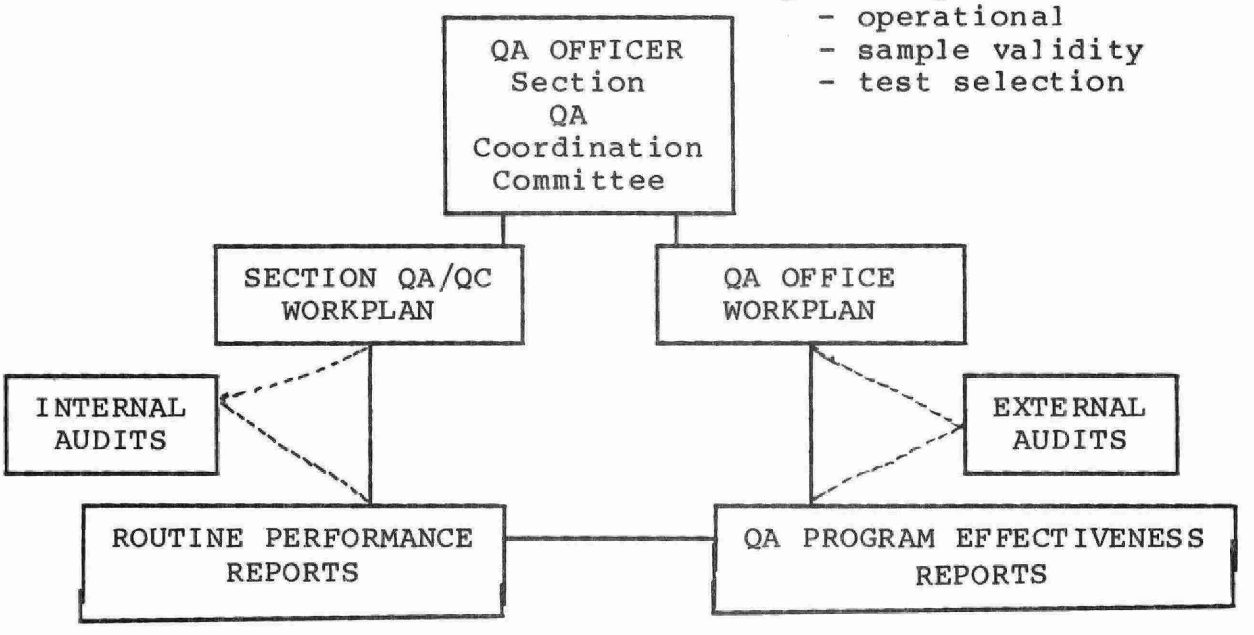


Figure 2

QUALITY MANAGEMENT DOCUMENTATION

GUIDANCE DOCUMENTS	SECTION (WORKING) DOCUMENTS
- QM Plan	- QM Strategy
- Code of Practice	- QA Program/Protocols
- QA Policies & Guidelines	- QA Business Plan
- Project Data Quality Objectives	- Performance Requirements
- QM Business Plans	- Performance Summaries
- Operational Protocols	- Analytical Protocols
- QA Office Documents	
- Audit Reports	- QA/QC Data/Records
	- Control Status Reports

Figure 3

1.7.2 Quality Assurance Protocols

These documents define specific activities required of staff. It will be derived from a consideration of the above Policy and Guidelines manual, whereby the more critical facets of laboratory operation will be formalized (e.g. method approval, data reporting, etc).

1.7.3 Quality Control Manual

These documents define the recommended QC protocols and procedures available for routine use by staff. These may be subject to revision within the Section QC Manual where such is warranted (e.g. control charting approaches, use of control samples and materials, container cleaning protocols).

1.7.4 Methods Manuals

These documents describe the individual analytical procedures undertaken in the Laboratories. Overall coordination, classification, approval and distribution is handled by the QA office staff. Individual method documentation is the responsibility of the Manager and staff of the Sections according to formats and protocols developed by the QA Office and Sectional QA Coordinators.

1.7. 5 Quality Assurance Office Business Plan

This document outlines the scheduled tasks of QA Office staff in support of the Branch and Section QA programs. It will be updated regularly (at least annually).

1.8 SECTION QUALITY ASSURANCE DOCUMENTATION

The Director of the Laboratory Services Branch hereby formalizes the responsibility of each Manager and Regional Laboratory Chief to implement and maintain a comprehensive and fully documented Section Quality Assurance Program. The following documents are essential components of a comprehensive Quality Assurance program. (See Figure 3.)

1.8.1 Section QM Strategy

This document defines how operations and data quality will be managed within each Section. It assigns to staff specific responsibilities with respect to the management, documentation, and reporting of QA/QC information and activities. It also establishes the Section Technical Committee and/or Section QA Coordinator to oversee all QA/QC related activity within the Section in cooperation with the QA Office.

1.8.2 Section QA Protocols

This document specifies, for each workstation and test procedure, those operations, equipment, reagents or other supplies, which are considered critical for maintaining data and operational quality. It identifies the specific protocols to be followed to ensure quality, the control limits, and remedial actions to be taken when limits are exceeded. This document forms the basis for System and Performance audits. This document is traceable to the Laboratory Quality Assurance Protocols (1.7.2).

1.8.3 Section QC Manual

This document describes the protocols and procedures to be followed within the Section to establish, maintain and record the quality of all analytical operations. It includes the process for obtaining approval to restart an analytical system when a problem has been identified. This document has direct linkage and traceability to the Laboratory Quality Control Manual (1.7.3).

1.8.4 Section Methods Manual

This document must encompass all analytical procedures that have been or may be employed within the Section. All methods must be fully documented, and subjected to management and QA Office review and approval prior to use. All method descriptions must be available on request.

1.8.5 Section Analytical Performance Reports

The performance characteristics of all analytical procedures must be available for scrutiny at all times, and be summarized regularly. In general, operational quality must include up-to-date control charts.

1.8.6 Section QA Workplan

This workplan, as an essential element of the annual Business Plan, identifies the specific tasks to be accomplished, the persons responsible, and anticipated completion dates, in order to achieve the activities identified in the Laboratories and Section Quality Management Plan/Strategy. It will be updated regularly (at least annually). A copy of the approved Section QA Workplan shall be provided to the QA Office.

2. STAFF QUALITY MANAGEMENT RESPONSIBILITIES

2.0 INTRODUCTION

The Quality Management Plan involves interaction between the Director, Laboratory Services Branch, the Section Managers, the Regional Laboratory Chiefs, and the Quality Assurance Office, to establish and manage the Branch Quality Assurance Program. These persons are particularly responsible for defining and documenting the QM/QA/QC duties of all staff and ensuring that they are understood and implemented.

The specific QM responsibilities of these individuals and committees are assigned in this chapter.

2.1 DIRECTOR'S QM RESPONSIBILITIES

a) Ensure that the Branch Quality Management Plan is implemented by Section Managers, Regional Laboratory Chiefs, and the Quality Assurance Officer;

b) Establish and chair a Central and Regional Laboratories Quality Assurance Committee to ensure a consistent approach to data and operational quality management;

c) Establish and chair a Laboratory Users Committee to participate with personnel from other Branches to determine analytical workloads and assist in defining the quality and type of service required;

d) Ensure monthly meetings of the Managers, to identify and resolve problems relating to workload and quality management;

e) Ensure that Branch protocols and procedures with respect to data quality management are exposed to peer review, and that they meet accepted international standards.

2.2 SECTION MANAGERS AND REGIONAL LABORATORY CHIEFS

a) Ensure that the quality of all analytical procedures under their control is managed and documented in accordance with the Laboratories Quality Management Plan;

b) Define the Section Quality Management Strategy and identify the individual responsible for Section QA Coordination;

c) Establish a Section Technical Committee to assist the Section QA Coordinator in developing and implementing the Section QA Workplan;

d) Work with the Laboratory Services Branch QA Office in setting their Section QA goals and objectives, in identifying and resolving problems, and in scheduling laboratory QA audits;

e) Ensure that staff participate in the various system and performance audits that may be scheduled;

f) Participate in the quarterly Central and Regional Laboratories QA Committee meetings, to advise on the progress of their QA Program, and to approve and ensure the adoption of Branch QM/QA/QC protocols relevant to their Section;

g) Provide such assistance as may be required to ensure all goals of the Laboratories Quality Management Plan are achieved;

h) Maintain regular contact with clients to discuss data quality needs.

2.3 QUALITY ASSURANCE OFFICE

The Quality Assurance Officer shall:

a) Oversee and report on the adequacy of all QM/QA/QC activities undertaken by Laboratory Managers, Regional Laboratory Chiefs and their staff in accordance with their responsibilities as outlined in 2.5 below;

b) In response to the Director, Managers and Regional Laboratory Chiefs coordinate the Section Technical Committees to ensure a consistent approach in the development of QM/QA/QC policies and directions;

c) Provide information and training to all laboratory staff on QA/QC, as it applies to routine analytical activities, including approaches to control-charting and statistical techniques;

d) Develop and circulate guidelines for consideration by project, field, and laboratory personnel in the development of relevant QA Programs and finalize adopted guidelines as ministry policies and protocols;

e) Advise Laboratory and Program Managers of any QA needs which will enhance the quality of Ministry programs, particularly where they impact on the quality of samples submitted to the laboratories.

Additionally, through the Quality Assurance Office, the Quality Assurance Officer shall ensure that staff:

a) Assist senior staff in determining and meeting the data quality requirements of all Ministry programs;

b) Oversee the development and implementation of a documented Quality Management System, and to evaluate each Section and Regional QA Program;

c) Advise Regional and Sectional Technical Committees in all aspects of operational and data quality maintenance, assessment, and documentation;

d) Establish regular QA Program Audits to ensure that QA/QC procedures are being implemented, data quality is being documented, and problems are being resolved;

e) Establish regular Performance Audits of analytical systems through submission of blind check samples/standards, and by monitoring and evaluating performance in interlaboratory comparison studies;

f) Assist Program Managers in auditing the performance of field operations by means of field blanks, control standards, and other appropriate measures;

g) Prepare and circulate such documents as are required to establish a consistent approach to the reporting and interpretation of analytical data;

h) Ensure that appropriate checks are performed on those laboratories contracted to provide analytical services;

i) Prepare and validate control and performance audit standards and samples for use by field and laboratory personnel in documenting the quality of their work, and by the QA Office in auditing performance.

2.4 OTHER BRANCH AND REGIONAL LAB STAFF

2.4.1 Supervisors shall:

a) Ensure that all analytical systems are operated in a state of statistical control;

b) Ensure that all analytical procedures are fully documented and that QA/QC requirements are defined and implemented;

c) Ensure that all method approval protocols are followed;

d) Ensure that staff are advised of the process for stopping and re-initiating analyses when problems have been flagged by the QA/QC process;

2.4.2 Senior Analysts/Project Leaders/Method Development Analysts shall:

a) Verify that QA/QC tasks are carried out as required;

b) Provide documentation of methods, procedures and protocols, and prepare quality assessment reports based on regular review of analytical QC records and observations;

c) Ensure that new methods are properly tested for ruggedness and reliability and are suitable for the samples to be analysed;

d) Ensure that method precision, accuracy, biases, recovery and specificity are properly documented and reported to the Section Technical Committee;

e) Ensure that no analytical process is implemented without manager approval;

f) Follow Good Laboratory Practices at all times when specific QA/QC protocols have not been defined;

g) Ensure that staff perform all required QA/QC tasks in accordance with established Section QA/QC protocol;

h) Ensure that all instances of system or component control failure are documented and problems resolved before reinstating or continuing the process.

2.4.3 Other Analysts and Staff shall:

a) Carry out their regular duties in accordance with the QA/QC protocols established within their Section or Regional Laboratory;

b) Carry out the QA/QC tasks assigned, record the results of all QC checks in the required format, and maintain such records so they are available and data quality can be traced and verified;

c) Assist in identifying and resolving operational or data quality problems;

d) Document all instances of failure to meet the required control limits, report them to the appropriate unit leader or supervisor and obtain supervisory approval to proceed.

2.5 CENTRAL/REGIONAL LABORATORIES QA COMMITTEE

Quarterly meetings are held between the Section Managers and the Regional Laboratory Chiefs, chaired by the Director, Laboratory Services Branch. The QA Office and Section QA Coordinators present highlight reports on the status of their QM Workplan. Recommendations for QM/QA/QC and related protocols or procedures shall be presented for final approval by this committee.

2.6 QA COORDINATION COMMITTEE

Regular meetings are held between the QA Officer and the Section QA Coordinators to ensure a consistent Ministry-wide approach to analytical data quality, documentation and data interpretation; to document these practices for management approval, and to respond to requests for information or protocol review, and development from the Laboratory Managers.

2.7 SECTION TECHNICAL COMMITTEE (STC)

Each Section Manager maintains a Section Technical Committee to coordinate and manage Section technical and QA/QC activities. The STC includes the Supervisors, the Branch Quality Assurance Officer plus other designated staff.

The STC, chaired by the Section QA Coordinator, is responsible for the development, documentation, and implementation of the Section Quality Assurance Program. It meets regularly to review existing QA/QC and analytical procedures, identify problems, recommend essential QA/QC activities, define protocols, and report on progress. Agendas are prepared, as well as minutes, and other progress reports as required. The Manager, Director, and Quality Assurance Office are copied on all such documents.

In particular each Section Technical Committee will:

a) Document the Section Quality Assurance Program and ensure its implementation on a unit-by-unit basis;

b) Prepare and schedule a Section QA Workplan which identifies the specific tasks assigned to staff and deadlines for completion,

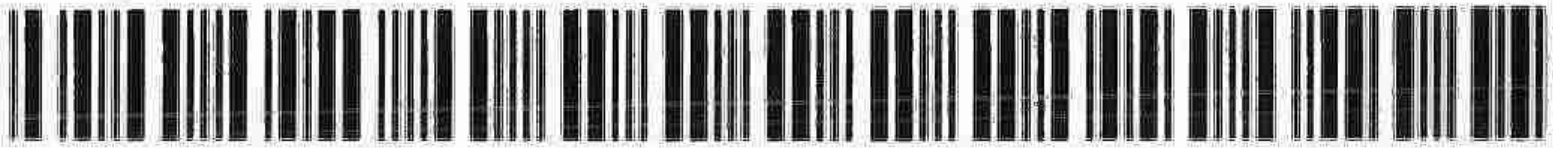
c) Ensure that all analytical and quality control procedures required are documented in the appropriate Section Method, QA, or QC manuals;

d) Ensure that the performance characteristics of all analytical systems are documented, and that appropriate control limits are established to maintain optimum performance;

e) Document all changes in Method or Quality Control protocols and procedures;

f) Participate in the development, documentation, and implementation of protocols related to the measurement, reporting, interpretation, or management of analytical data;

g) Participate in Sectional system, analytical and performance audits.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